EXHIBIT C

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION *As to All Related and Member Cases*	Case No. 13-md-2452-AJB-MDD **DEFENDANT MERCK SHARP & DOHME CORP.'S AMENDED RESPONSES AND OBJECTIONS TO PLAINTIFFS' GENERAL CAUSATION INTERROGATORIES** Judge: Hon. Anthony J. Battaglia Magistrate: Hon. Mitchell D. Dembin

Defendant Merck, Sharp & Dohme Corp. ("Merck"), pursuant to the Federal Rules of Civil Procedure, sets forth below its Responses and Objections to Plaintiffs' General Causation Interrogatories.

samples, etc.) provided to the EMA, and any study protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.) not provided to the EMA.

ANSWER: Merck objects to this interrogatory to the extent it seeks information on drugs other than JANUVIA® or JANUMET®. Merck has produced its EMA regulatory files for JANUVIA® and JANUMET®, but only under the unique and specific facts of this case, namely, that Merck references the EMA's July 2013 Assessment in support of its defenses in this case. The EMA documents were produced at MRKJAN0001369341-MRKJAN0003005722. Merck maintains its position that regulatory filings with foreign agencies are generally irrelevant to product liability actions in the United States and objects to interrogatories concerning other foreign agencies as overly broad and unduly burdensome. Merck otherwise incorporates its response to Interrogatory Number 2, 4, 7, 10 and 13 as if set forth fully herein.

INTERROGATORY NO. 17: If any such other study, test, investigation, evaluation and/or assessment YOU are aware of that bears, in whole or in part, on whether JANUVIA AND/OR JANUMET CAUSES and/or is capable of CAUSING pancreatic cancer (whether such study, test, investigation, evaluation and/or assessment involves JANUVIA AND/OR JANUMET, another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug) has not yet been started or completed, describe the nature and intended purpose of each such study, and identify the person(s) in charge of each.

ANSWER: Merck objects to this interrogatory as overly broad and unduly burdensome to the extent that it asks Merck to identify studies conducted by third parties concerning the safety profile of JANUVIA® and JANUMET® and/or other incretin-based therapies. Information publicly available is equally accessible by

Plaintiffs. Merck states that the scientific evidence does not support the allegation that JANUVIA® and/or JANUMET® causes and/or is capable of causing pancreatic cancer. An assessment by the FDA and EMA concluded that "[b]oth agencies agree that assertions concerning a causal association between incretin-based drugs and pancreatitis or pancreatic cancer, as expressed recently in the scientific literature and in the media are inconsistent with the current data." *See* Amy G. Egan, et al., Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment, N. Eng. J. Med. 794 (Feb. 27, 2014).

Merck provides literature references relating to sitagliptin in connection with many of its submissions to the FDA. For example, Merck submits annual reports to the FDA relating to the NDAs for JANUVIA® and JANUMET®, each of which includes a comprehensive listing of published clinical trial literature for the applicable reporting period. *See* MRKJAN0000167557-MRKJAN0000167597; MRKJAN0000338592-MRKJAN0000338594; MRKJAN0000173092-MRKJAN0000173161; MRKJAN0000344982-MRKJAN0000344986; MRKJAN0000194776-MRKJAN0000194851; MRKJAN0000352210-MRKJAN0000352212; MRKJAN0000202702-MRKJAN0000202819; MRKJAN0000355672-MRKJAN0000355681; MRKJAN0000205171-MRKJAN0000205343; MRKJAN0000358532-MRKJAN0000358544; MRKJAN0000365311-MRKJAN0000365480; MRKJAN0000371537-MRKJAN0000371543; MRKJAN0000895237-MRKJAN0000895549.

Merck's Period Safety Update Reports for JANUVIA® and JANUMET® include information about published safety studies that describe new and potentially important safety information relating to sitagliptin. *See, e.g.*, MRKJAN0000191286. Moreover, the Investigator's Brochure, which is issued and filed with the FDA periodically to provide an updated clinical profile of JANUVIA®, includes references

to support each of its sections. *See, e.g.*, MRKJAN0000367991-MRKJAN0000368135.

INTERROGATORY NO. 18: Do YOU contend that any one study, test, investigation, evaluation and/or assessment (whether such study, test, investigation, evaluation and/or assessment involves JANUVIA AND/OR JANUMET, another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug), establishes that JANUVIA AND/OR JANUMET does not CAUSE and/or is not capable of CAUSING pancreatic cancer? If so, explain your answer.

ANSWER: Merck objects to this interrogatory to the extent it seeks information on drugs other than JANUVIA® or JANUMET®. Any conclusions about the relationship between JANUVIA® and/or JANUMET® and pancreatic cancer must be based on a comprehensive analysis of available and reliable scientific evidence. The data do not demonstrate that JANUVIA® or JANUMET® is associated with an increased risk of pancreatic cancer.

INTERROGATORY NO. 19: Identify each pancreatitis and pancreatic cancer ADVERSE EVENT that YOU are aware of with respect to JANUVIA AND/OR JANUMET (whether it arose from pre-market or post-market use) that YOU deemed to be related to the patient's use of JANUVIA AND/OR JANUMET, including its Bates number (if already produced), date, name of the author/reporter, and the location from which the ADVERSE EVENT was reported.

ANSWER: Merck objects to the term "related to" in this interrogatory as vague and ambiguous, particularly as to whether it refers to a causal relationship. Merck objects to Plaintiffs' characterization that adverse event reports can individually be used to assess whether a drug caused the adverse event. Merck has produced MedWatch forms for global adverse event reports of pancreatitis and pancreatic cancer for

sitagliptin through February 28, 2014. The MedWatch forms were produced at Bates ranges MRKJAN0000375281-MRKJAN0000381778; MRKJAN0000953048-MRKJAN0000954328; MRKJAN0001368733- MRKJAN0001368912. Merck also has produced so-called "native" or "quasi-native" data files extracted from its database for global adverse event reports of pancreatitis and pancreatic cancer for sitagliptin received through February 28, 2014. The data includes fields used by Merck in the ordinary course of business, but does not include fields containing personal identifying information. Merck has produced these data extractions in Access Database format. Further, Merck has produced documents relating to adverse events for sitagliptin in its IND and NDA files for JANUVIA® and JANUMET® and in its further production of clinical trial materials.

INTERROGATORY NO. 20: Identify each pancreatitis and pancreatic cancer ADVERSE EVENT that YOU are aware of with respect to JANUVIA AND/OR JANUMET (whether it arose from pre-market or post-market use) that YOU did not deem to be related to the patient's use of JANUVIA AND/OR JANUMET, including its Bates number (if already produced), date, name of the author/reporter, and the location from which the ADVERSE EVENT was reported.

ANSWER: Merck objects to the term "related to" in this interrogatory as vague and ambiguous, particularly as to whether it refers to a causal relationship. Merck objects to Plaintiffs' characterization that adverse event reports can individually be used to assess whether a drug caused the adverse event. Merck has produced MedWatch forms for global adverse event reports of pancreatitis and pancreatic cancer for sitagliptin through February 28, 2014. The MedWatch forms were produced at Bates ranges MRKJAN0000375281-MRKJAN0000381778; MRKJAN0000953048-MRKJAN0000954328; MRKJAN0001368733- MRKJAN0001368912. Merck also has produced so-called "native" or "quasi-native" data files extracted from its

medical incident as an adverse event, and Merck does not make any independent determination as to whether any such incident is an "adverse event."

INTERROGATORY NO. 23: Itemize and explain the criteria YOU use to determine whether an ADVERSE EVENT is related to a patient's use of JANUVIA AND/OR JANUMET, and identify the DOCUMENTS that list and/or explain those criteria.

ANSWER: Merck objects to the term "related to" in this interrogatory as vague and ambiguous, particularly as to whether it refers to a causal relationship. Merck objects to Plaintiffs' characterization that adverse event reports can individually be used to assess whether a drug caused the adverse event.

Merck's policies and practices with respect to spontaneous and clinical trial adverse event reports were described in detail in the February 26, 2014, 30(b)(6) deposition of Linda Hostelley. Pursuant to regulations and pharmacovigilance principles, Merck conducts aggregate analyses of spontaneous post-marketing reports to assess whether the reports suggest a need for further investigation of a potential safety signal. Merck does not make determinations as to whether any one spontaneous postmarketing adverse event is related to the use of JANUVIA® or JANUMET®. The procedures for this process are contained in Standard Operating Procedure 230-PV001 (MRKJAN0000892492-MRKJAN0000892547), as well as parts of the MARRS Manual (MRKJAN0000892548-MRKJAN0000893196). In addition, since 2009 Merck's clinical trial personnel have performed "Company Causality Assessments" of certain individual adverse events reported to the Company from sitagliptin clinical trials. The procedures for Company Causality Assessments are set forth in Standard Operating Procedure 210-PV004 (MRKJAN0000892159-MRKJAN0000892165), as well as parts of the MARRS Manual (MRKJAN0000892548-MRKJAN0000893196). Merck's trending analysis on

JANUVIA® and JANUMET® has not revealed that either drug causes pancreatitis or pancreatic cancer.

In addition, Merck's JANUVIA® Risk Management Safety Team ("RMST") is a cross-functional team responsible for overall risk management and safety signal evaluation for JANUVIA® and JANUMET®, including pancreatic safety issues, and Merck's Safety Review Committee ("SRC") is responsible for reviewing preclinical and clinical safety-related findings impacting both developmental and marketed products, as well as for reviewing emerging signals and findings from post-marketing safety assessment. Relevant, non-privileged documents from the SharePoint sites for each of these groups have been produced to Plaintiffs. The SRC documents were produced at MRKJAN0000928460-MRKJAN0000931930. RMST is a subteam of the JANUVIA® Product Development Team ("PDT"), and the RMST-related documents are included within the production of documents collected from the PDT SharePoint site, which was produced at MRKJAN0000931938-MRKJAN0000953047.

INTERROGATORY NO. 24: Identify all medical and/or scientific literature YOU are aware of, including studies, editorials and/or peer-reviewed articles, that relates to the association between JANUVIA AND/OR JANUMET or any other GLP-1 agonist or DPP-4 inhibitor and pancreatitis and/or pancreatic cancer.

ANSWER: Merck objects to this interrogatory to the extent it seeks information on drugs other than JANUVIA® or JANUMET®. Merck states that in assessing drug safety, Merck reviews all of the safety data on a drug reasonably available to it. Merck provides literature references relating to sitagliptin in connection with many of its submissions to the FDA. For example, Merck submits annual reports to the FDA relating to the NDAs for JANUVIA® and JANUMET®, each of which includes a comprehensive listing of published clinical trial literature for the applicable reporting